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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,705	02/21/2002	John Barthelow Classen	22499-68466	1273

23973 7590 01/04/2007

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EXAMINER	
LEROUX, ETIENNE PIERRE	
ART UNIT	**PAPER NUMBER**
2161	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,705	CLASSEN, JOHN BARTHELOW	
	Examiner	Art Unit	
	Etienne P LeRoux	2161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *250-294* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *250-294* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ___ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Status:

Claims 250–294 are pending: claims 1-249 have been cancelled. Claims 250-294 are rejected as detailed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 250 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 250 recites "identifying at least one new essential adverse event associated with the product or device from the adverse event data, and then responsive to identification, identifying the at least one new characteristic of, or use for, the product or device." Applicant failed to point to the specification for support of above limitation. The specification does not describe how the new essential adverse event is derived from the adverse event data sources.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 250 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 250 recites "creating a proprietary essential adverse event information database which stores data regarding the at least one new characteristic or use, wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication." The metes and bounds of the present invention is unclear because Applicant claims a database of "essential adverse event information" which is patentable. The present application in the preamble states "A proprietary new use for, or characteristic of, a product." The scope of the present invention is unclear because Applicant is attempting to obtain two patents for essentially the same thing. Because both in the database of "essential adverse event information" and the present application, the new for the product and the essential adverse information must be included. For purposes of this Office action, above limitation will not be given patentable weight.

Claim 250 recites:

one data source comprises adverse event data

one previously known adverse event

identifying at least one new essential adverse event

proprietary adverse event information

The metes and bounds of the present invention cannot be determined because it is unclear what difference, if any, exists between above claim elements. For purposes of this Office action, examiner assumes **no** (emphasis added) difference exists between above claim elements.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 250 is rejected under 35 U.S.C. 101 because the claimed invention preempts a 35 U.S.C. 101 judicial exception of natural phenomenon.

MPEP § 210 states the phenomena of nature, though just discovered, mental processes, abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." Benson, 409 U.S. at 67, 175 USPQ at 675. The present application claims "new essential adverse event." Interpreting "new essential adverse event" in light of the specification, new "essential adverse event" may be birth defects or drug interactions in animals. Birth defects and drug interactions in animals are phenomena of nature. Furthermore, "new characteristic of, or user for, the product" is claimed. Interpreting "new characteristic of, or user for, the product" in light of the specification, "new characteristic of, or user for, the product" may be restricted use of the product. The usage or dosage of the product which causes an adverse event in humans or animals is a phenomenon of nature and is not statutory patentable subject matter.

Furthermore, the present invention does not have real world value, i.e., it is not useful, concrete and tangible. The present invention claims "A new use for a product" for a product that is well-known and expected in the art. MPEP § 2105 states "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas

Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 250, 256 and 257 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat No 6,000,828 issued to Leet (hereafter Leet) in view of US Pat No 5,991,751 issued to Rivette et al (hereafter Rivette), as best examiner is able to ascertain.

Claim 250 and 256:

Leet discloses:

accessing one or more data sources [Fig 2]

wherein at least one data source comprises adverse event data [Fig 2, drug interactions database 28e, col 26, lines 5-61]

analyzing and comparing adverse event data associated with a product of manufacture or device, with at least one previously-known adverse event associated with the product or device; [detect any drug interactions, col 18, lines 60-65]

identifying at least one new essential adverse event associated with the product or device from the adverse event data, and then responsive to identification, identifying the at least one new characteristic of, or use for, the product or device [pharmacist performs reviews, col 18, lines 55-60]

documenting inventorship of the at least one new characteristic of, or use for, the product or device [message is sent to the physician, col 19, lines 5-10]

creating a proprietary essential adverse event information database which stores data regarding the at least one new characteristic or use [drug interactions database 28e, col 26, lines 5-61]

Leet discloses the elements of the claimed invention as noted above but does not include wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication. Rivette discloses wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication [Rivette abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Leet to include wherein the database comprises at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication as taught by Rivette for the purpose of managing an inventor's database of intellectual property.

Claim 257:

The combination of Leet and Rivette disclose the elements of claim 250 as noted above but does not disclose sales data. Official Notice is taken that sales data is well-known and

expected in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information for the purpose of determining the value of commercializing a product.

Claims 251, 252, 254 and 258 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Leet and Rivette and further in view of US Pat No 5,678,234 issued to Colombo et al (hereafter Colombo), as best examine is able to ascertain.

Claims 251, 252 and 254:

The combination of Leet and Rivette discloses the elements of claim 250 as noted above but does not disclose determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event. Colombo discloses determining value of commercializing the at least one new characteristic or use determined from the at least one identified essential adverse event [col 3, lines 60-65].

Claim 258:

The combination of Leet, Rivette and Colombo discloses the elements of claims 250-252 as noted above and furthermore discloses a drug interaction [col 18, lines 50-65]

Claims 253 and 255 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Leet, Rivette and Colombo and further in view of US Pat No 6,018,714 issued to Risen et al (hereafter Risen), as best examiner is able to ascertain.

Claim 253 and 255:

The combination of Leet, Rivette and Colombo discloses the elements of claims 250-252 as noted above but does not disclose the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information. Risen discloses the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the above combination of references to include the commercializing step further comprising generating information for incorporation into documents for selling, leasing or licensing the newly identified product information as taught by Risen for the purpose of deriving income from intellectual property.

Regarding claims 259-293, examiner maintains that such claims can be rejected over the prior art made of record.

Response to Arguments

Applicant's arguments submitted 11/24/2006 have been considered but are moot based on the new grounds of rejection required for newly presented claims 250-294.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Pat No 6,243,615 issued to Neway et al discloses an Adverse Event Management System 208, Fig 2.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne P. LeRoux whose telephone number is (571) 272-4022. The examiner can normally be reached Monday through Friday, 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Gaffin can be reached on (571) 272-4146. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Etienne LeRoux

12/26/2006

Etienne P LeRoux
primary examiner